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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/077,572 10/13/98 APICELLA

M 875001US2

EXAMINER

HM12/0221

SCHWEGMAN LUNDBERG WOESSNER & KLUTH  
PO BOX 2938  
MINNEAPOLIS MN 55402

DEVILS

ART UNIT

PAPER NUMBER

1645

27

DATE MAILED:

02/21/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/077,572

Applicant(s)

Apicella et al.

Examiner

S. Devi, Ph.D.

Group Art Unit

1645

☒ Responsive to communication(s) filed on 12/08/2000.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 22-26, 29, 32, and 33 ~~is~~are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 22-26, 29, 32 and 33 ~~is~~are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

## **DETAILED ACTION**

### **Applicants' Amendment**

1) Acknowledgment is made of Applicants' amendment filed 12/08/00 (paper no. 26) in response to the non-final Office Action mailed 10/11/00 (paper no. 25). Amendment requested to be introduced to page 9, line 6 of the specification has NOT been entered, since there is no word "location" on page 9, line 6.

### **Status of Claims**

2) Claims 22, 29, 32 and 33 have been amended via the amendment filed 12/08/00.  
Claims 22-26, 29, 32 and 33 are pending and are under examination.

### **Objection(s) Maintained**

3) The objection to the drawings made in paragraph 6 of the Office Action mailed 04/28/99 (paper no. 11) under 37 CFR 1.84 because of the reasons set forth by the Draftsperson is maintained for reasons set forth therein. Applicants assure the Office that corrected formal drawings will be submitted upon notification of allowance of the claims.

### **Objection(s) Withdrawn**

4) The objection to claims 32 and 33 made in paragraph 27 of the Office Action mailed 10/11/00 (paper no. 25) is withdrawn in light of Applicants' amendments to the claims.

### **Rejection(s) Maintained**

5) The rejection of claims 22, 23, 25 and 29 made in paragraph 9 of the Office Action mailed 04/28/99 (paper no. 11) under the judicially created provisional obviousness type double patenting is maintained for reasons set forth therein. Applicants state that if appropriate, they will consider filing a terminal disclaimer upon notification of allowable subject matter.

6) The rejection of claims 22-26 and 29 made in paragraph 10 of the Office Action mailed 04/28/99 (paper no. 11) under 35 U.S.C. § 112, first paragraph, with regard to the deposit of the mutant bacterium is maintained for reasons set forth therein. Applicants have submitted a copy of ATCC deposit receipt showing that non-typeable *Haemophilus influenzae* 2019 B28 and 2019 strains have been deposited under the provisions of the Budapest Treaty and provided the

statement that all restrictions will be irrevocably removed upon the granting of a patent in compliance with 37 CFR 1.801-1.809. However, the amendment requested by Applicants at page 9, line 6 after the recitation "location" remains unentered, since there is no such recitation on page 9, line 6. Since Applicants have not fully complied with 37 C.F.R 1.801-1.809, the rejection will be maintained currently.

7) The rejection of claim 32 made in paragraph 23 of the Office Action mailed 10/11/00 (paper no. 25) under the judicially created provisional obviousness type double patenting over the cited claim(s) of application SN 09/565,943 is maintained for reasons set forth therein. Applicants state that if appropriate, they will consider filing a terminal disclaimer upon notification of allowable subject matter.

8) The rejection of claims 22, 29, 32 and 33 made in paragraph 24 of the Office Action mailed 10/11/00 (paper no. 25) under 35 U.S.C. § 112, first paragraph, as failing to provide an enabling disclosure, with regard to the deposit issue, is maintained for reasons set forth above in paragraph 6.

#### **Rejection(s) Withdrawn**

9) The rejection of claims 22, 23, 25 and 32 made in paragraph 25 of the Office Action mailed 10/11/00 (paper no. 25) under 35 U.S.C. § 103(a) as being unpatentable over Karow *et al.* (*J. Bacteriol.* 174: 7407-7418, 1992) in view of Westphal *et al.* (*Methods Carbohydr. Chem.* 5: 83-91, 1965), is withdrawn in light of Applicants' amendments to the base claim.

10) The rejection of claims 22, 23, 25 and 32 made in paragraph 26 of the Office Action mailed 10/11/00 (paper no. 25) under 35 U.S.C. § 103(a) as being unpatentable over Karow *et al.* (*J. Bacteriol.* 174: 7407-7418, 1992) in view of Westphal *et al.* (*Methods Carbohydr. Chem.* 5: 83-91, 1965) is withdrawn in light of Applicants' amendments to the base claim.

#### **New Rejection(s)**

Applicants are asked to note the new rejections made in this Office Action. The Applicants' amendment necessitated the new grounds of rejections presented in this Office Action.

**Rejection(s) under 35 U.S.C. 112, First paragraph**

11) Claims 22-26, 29, 32 and 33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Base claims 22 and 29 currently include the limitation "and lacking 3-hydroxy unsaturated C16 fatty acid substitutions on the lipid A as compared to a wild-type bacterial pathogen". However, there appears to be no descriptive support in the instant specification for the newly added limitation. Applicants have pointed to page 7, lines 23-26, page 13, lines 1-5 and Figures 2A and 2B of the specification as supporting the newly added limitation or amendment to the claims. However, these parts of the specification do not provide descriptive support for the newly added limitation.

The new limitation in the claims is therefore considered to be new matter. *In re Rasmussen*, 650 F.2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P. 608.04 to 608.04(c).

Applicants are respectfully requested to point exactly to the descriptive support in the specification as filed, for the newly added limitation, or to remove the new matter from the claims.

**Remarks**

12) Claims 22-26, 29, 32 and 33 stand rejected.

13) **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1 (CM1). The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242, which receives papers 24 hours a day, seven days a week.

15) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A telephone message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
S. Devi, Ph.D.  
Patent Examiner  
February 2001